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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/509,951
Filing Date: October 04, 2004
Appellant(s): PEREZ-CAMARGO ET AL.

Robert M. Barrett
Reg. No. 30,142
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/28/10 appealing from the Office action mailed 12/08/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 35, 45, 48-52 and 57-64.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter

contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

Claims 35, 45, 48-52 and 57-64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

6,471,999	Couzy et al.	10-2002
6,524,619	Pearson et al.	02-2003
6,228,367	Watson et al.	05-2001
6,160,007	DeMichele et al.	12-2000
WO 01/62280	Margolin et al.	08-2001
WO 02/15719	Fuchs et al.	02-2002
Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease, Proceedings ACVIM,	Simpson et al.	2001

Denver, CO, pp. 651-653, 2001.		

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection 1:

1. Claims 35, 45, 48-52 and 57-64 are rejected 35 U.S.C. 103(a) as being unpatentable over Couzy et al. (USP 6,471,999) in view of Pearson et al. (USP 6,524,619) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease, Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS), Watson et al. (USP 6,228,367), DeMichele et al. (USP 6,160,007) and Margolin et al. (W0 01/62280).

Couzy et al. teach a pet milk powder as nutritional milk those results in reduced gastrointestinal intolerance (abstract). Couzy et al. teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, **taurine (a liver function promoter as claimed),** arginine and choline (claims 1-9; col. 2, lines 9-lines 26).

Couzy et al. teaches that a protein source of whey protein and further supplemented with **taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40)**. (Lactic acid reads on pancreatic function promoter, therefore, it is obvious that an acidifier such as lactic acid produced by probiotics help in improving intestinal balance, it is to be noted that probiotics are known to produce lactic acid and acetic acid, a pH modifying agent, which inhibit growth of bacteria, see instant specification page 8, paragraph 30).

Couzy et al. teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14).

Couzy et al. teach that the amount of nutritional composition is to be fed to a mammal each day depends on factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), **vitamins,** minerals, and soybean oil, and adding water to provide nutritional supplement to **dogs and puppies or cats**. Couzy et al. teaches that a protein source of whey protein and further supplemented with taurine and a **probiotic micro-organism** which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). Couzy et al. teach omega fatty acids such as **soybean oil (**It is to be noted that fish oil is known in the art to comprise omega fatty acids such as EPA and DHA ,see USP 6,608,223) and in Examples 1-2 (col. 3, lines 15-20). **Soybean oil and vitamin** has been shown to be at

1.7 percent by weight and 0.4% by weight respectively in Example 1 in column 4. The amount of soybean oil (which comprises omega fatty acid reads on a fatty acid with profile as claimed in instant claim 45) is within the claimed range of from about 0.1% to 20%.

The reference by Couzy et al. as disclosed above does not teach correlation of taurine with lipid absorption and correlation of lipid absorption with vitamin E levels.

Pearson et al. teach that taurine enhances absorption of drug especially lipid soluble drugs and also teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25.

Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health. (See the entire article/reference of record).

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by Couzy et al. in order to help in lipid absorption motivated by the teachings of Pearson et

al. and would expect improvement in vitamin E absorption in light of the teachings of Simpson et al. which teaches that vitamin E deficiency occurs due to defect in lipid absorption.

It would have been obvious to one of ordinary skill in the art to optimize the amount of liver function promoter such as taurine to obtain best possible results by doing experimental manipulations because Couzy et al. teaches soybean oil (reads on both liver function promoter and intestinal function promoter as taught in instant specification) and vitamins in 1.7% and 0.4% amount (claimed as liver function promoter in instant specification), as such it would have been within the purview of a skilled artisan to optimize the amount of the claimed liver function promoter, **taurine** to obtain best possible results of lipid absorption and vitamin E absorption and come to the claimed invention with a reasonable expectation of success.

The teachings of references discussed above teach omega 3 fatty acids, however the references do not specifically teach fish oil in the composition.

Watson et al. claims in claim 1 a food supplement formulation of **fish oil** and lipase (the instant specification defines a fish oil to be intestinal mucosa function promoter). The supplement of Watson et al. improves bodily functions including fat metabolism, etc (col. 2, lines 26-30). The fish oil has specific fatty acid profile.

It would have been obvious to one of ordinary skill in the art to utilize fish oil in the teachings of primary references in order to improve fat metabolism motivated by the teachings of Watson et al... It would have been further obvious to one of ordinary to substitute fish oil in the teachings of the references discussed above because Couzy et

al. teaches inclusion of omega fatty acids in the composition and fish oil is known in the art to comprise omega fatty acids as is evident by USP 6,608,223.

The teachings of combined references taught above do not disclose correlation of fish oil (intestinal mucosa function promoter) with lipid absorption or vitamin E absorption.

DeMichele et al. teaches fish oil enhances absorption of vitamin E tocopherol and vitamin A, retinol and teaches lipid digestion and absorption in rat model, see example 2 in column 11 and 12, lines 60-68 and 1-5 respectively.

Additionally, Margolin et al. correlates the lipid absorption capacity with vitamin E absorption. As such, vitamin E absorption with the enhanced absorption of lipid in a pet animal would have been obvious to one of ordinary skill in the art by administration of a composition comprising fish oil, (an intestinal mucosa function promoter) in light of teachings of Watson et al., DeMichele et al., and Margolin et al. and taurine, (a liver function promoter) in light of teachings of Pearson et al as discussed above.

It would have been obvious to one of ordinary to have utilized fish oil for enhanced absorption of vitamin E motivated by the combined teachings of Watson et al., DeMichele et al., and Margolin et al. A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter (taurine), pancreatic function promoter (acidifier and pH regulating agent lactic acid and acetic acid as discussed above coming from probiotic bacteria) and intestinal function promoter (fish oil) with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet/cat animal. Since the references teach

lipid absorption due to taurine and vitamin E absorption due to fish oil and since amount of vitamins (a liver function promoter) have been disclosed to be within the claimed amount that is 0.4% as discussed above and amount of omega 3 fatty acids it be 1.7% as discussed above by Couzy's reference, experimental manipulations to obtain workable amounts of taurine (a liver function promoter) would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used, absent evidence to contrary.

Rejection 2:

2. Claims 35, 45, 48-52 and 57-64 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al (WO 02/15719) in view of Pearson et al. (USP 6,524,619) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease, Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS), Watson et al. (USP 6,228,367), DeMichele et al. (USP 6,160,007) and Margolin et al. (W0 01/62280, presented in IDS).

Fuchs et al disclose a method of treatment which comprises administering an effective amount of the composition which contains whey protein to improve, promote, maintain intestinal function and mucins a patient or **companion animal** (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21).

Example 4 teaches a nutritional supplement comprising whey protein and **probiotic bacteria**. (It is to be noted that probiotics are known to produce **lactic acid** and acetic acid, a pH modifying agent, which inhibit growth of bacteria, see instant specification page 8, paragraph 30).

Fuchs et al teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism (pancreatic function promoter as claimed) provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). The amount of Whey protein is taught to be 4.8% and **vitamins and minerals to at least 5%** of RDA in example 1 on page 13, Fuchs et al. also teaches including a probiotic (claim 13, pg. 5, and lines 27-30). Fuchs et al teach including **taurine and** (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), (claimed as liver function promoter in instant claims). Fuchs et al teach a lipid source including **omega-3 fatty acids** (abstract, claim 1). (Fish oil comprises omega 3 fatty acids and fish oil has been claimed as, an intestinal function promoter in instant claims).

Fuchs et al teach a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2). The reference teaches various amounts of polyunsaturated fatty acids including **omega 3 fatty acid** to be **15 to 30%,** see page 8,

lines 10-20. The reference teaches vitamins (claimed as liver function promoter in instant application), see page 9, and lines 1-14.

Fuchs et al. do not teach correlation of taurine with lipid absorption and correlation of lipid absorption with vitamin E levels.

Pearson et al. teach that taurine enhances absorption of drug especially lipid soluble drugs and also teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25.

Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health. (See the entire articles of record).

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by Fuchs et al. in order to help in lipid absorption motivated by the teachings of Pearson et al. and would expect improvement in vitamin E absorption in light of the teachings of

Simpson et al. which teaches that vitamin E deficiency occurs due to defect in lipid absorption.

While Fuchs et al. teach utilizing omega 3 fatty acids, the reference does not teach fish oil (which comprises omega 3 fatty acids) (claimed as intestinal mucosa function promoter).

Watson et al. claims in claim 1 a food supplement formulation of **fish oil and** lipase (the instant specification defines a pancreatic extract to be a lipase pg. 12, lines 1-3) (abstract, claim 1). The supplement of Watson et al. improves bodily functions including fat metabolism, etc (col. 2, lines 26-30). The fish oil has specific fatty acid profile.

It would have been obvious to one of ordinary to substitute fish oil in the teachings of the references discussed above because 'Fuchs et al. teach inclusion of omega fatty acids in the composition and fish oil is known in the art to comprise omega fatty acids as is evident by USP 6,608,223.

The teachings of combined references discussed above do not disclose correlation of fish oil (intestinal mucosa function promoter) with lipid absorption or vitamin E absorption.

DeMichele et al. teach fish oil enhances absorption of vitamin E tocopherol and vitamin A, retinol and teaches lipid digestion and absorption in rat model, see example 2 in column 11 and 12, lines 60-68 and 1-5 respectively.

Additionally, Margolin et al. correlates the lipid absorption capacity with vitamin E absorption. As such, vitamin E absorption with the enhanced absorption of lipid in a pet

animal would have been obvious to one of ordinary skill in the art by administration of a composition comprising fish oil, (an intestinal mucosa function promoter) in light of teachings of Watson et al., DeMichele et al., and Margolin et al. and also by administering taurine, (a liver function promoter) in light of teachings of Pearson et al as discussed above. It would have been obvious to one of ordinary to have utilized fish oil for enhanced absorption of vitamin E motivated by the combined teachings of Watson et al., DeMichele et al., and Margolin et al. references. A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter (taurine), pancreatic function promoter (acidifier and pH regulating agent lactic acid and acetic acid as discussed above coming from probiotic bacteria) and intestinal function promoter (fish oil) with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet/cat animal. Since the references teach lipid absorption due to taurine and vitamin E absorption due to fish oil and since amount of vitamins (a liver function promoter) have been disclosed to be within the claimed amount that is 0.4% as discussed above and amount of omega 3 fatty acids it be 4.8% and 5% and amount of omega fatty acids to be 15% as discussed above by 'Fuchs et al., experimental manipulations to obtain workable amounts of taurine (a liver function promoter) would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used, absent evidence to contrary.

(10) Response to Argument

Rejection 1:

Appellant argues that a *prima facie case* of obviousness has not been established by the office and the rejections shall therefore be withdrawn. Appellants argue that studies on senior cat nutrition have shown a significant number of older pets such as those above the age of 9 years-exhibit a decreased capacity to digest fat by referring to scientific publications such as Burkholder, W J., Age-related changes to nutritional requirements and digestive function in adult dogs and cats. JAVMA, Vol 215, No. 5, Sep. 1, 1999; Nicholson A, Watson A D J. Mercer J R., Fat malassimilation in three cats. Australian Veterinary Journal, Vol. 66, No. 4, April, 1989; Peachey S E, Dawson J M, Harper E J., The effects of aging on nutrient digestibility by cats fed beef tallow, sunflower oil or olive oil enriched diets. Appellants then contend that there can be any of a number of pathologies that can lead to poor digestibility of lipids and malabsorption and maldigestion can occur from almost any diffuse disease of the intestine, from exocrine pancreatic insufficiency or from unknown causes and further in the case of cats, pancreatitis occurs at a prevalence rate of about 0.15% to 3.5% and may account for some cases of poor fat digestibility, diffuse intestinal diseases, such as intestinal lymphoma, small intestinal bacterial overgrowth, inflammatory bowel disease and liver disease, may also lead to reduced nutrient absorption in the small intestine. Appellants further add that the references used in the rejection such as *Couzy,*

Pearson,Simpson, Watson, DeMiehele and Margolin alone or in combination fail to disclose or suggest a liver function-promoter comprising taurine ranging between about 0.1% and about 1% by weight of the edible composition on a dry matter basis as required independent Claims 35, 52 and 61 and also fail to disclose or suggest the specific combination of the acidifier, taurine and fish oil in a single edible composition for improving or maintaining absorption of vitamin E in a cat as recited by independent Claims 35, 52 and 61.

Appellants arguments are not persuasive, in response to appellants arguments that the claimed range of taurine is not taught by prior art, it is respectfully pointed out that Couzy et al. as discussed in the rejection does teach vitamins (described as liver function promoter in instant specification as discussed above in the rejection) in the claimed range which has been described in instant specification as liver function promoter, the reference also teaches inclusion of taurine in the composition, therefore one of ordinary skill would have envisaged utilizing either vitamin or taurine as liver function promoter with an expectation to obtain similar results because Couzy et al. teaches inclusion of taurine in pet food composition and Pearson et al. teaches that bile salts are synthesized in the liver from cholesterol conjugated with **taurine (claimed as liver function promoter)** and within the gastrointestinal lumen these bile salts play an **essential role in lipid absorption** and fat transport, see column 22 and 23, lines 63-68 and 15-25. (Thus it can be inferred that bile salt with taurine play important role in fat absorption). Additionally, since Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids and a defect in either the

absorption or digestion of lipid can lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids, one of ordinary skill would have envisaged utilizing taurine as vital component in the form of liver function promoter in order to promote lipid and thus vitamin E absorption with a reasonable expectation of success. Since the references teach lipid absorption due to taurine and vitamin E absorption due to fish oil and since amount of vitamins (a liver function promoter) have been disclosed to be within the claimed amount that is 0.4% as discussed above and amount of omega 3 fatty acids it be 1.7% as discussed above by Couzy et al., experimental manipulations to obtain workable amounts of taurine (a liver function promoter) would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used.

Appellants argue that the declaration provides unexpected results. Appellants argue that the claimed edible composition comprising an acidifier, taurine ranging between about 0.1% and about 1% by weight of the edible composition, and fish oil ranging between about 0.1% and 20% by weight of the edible composition creates a synergistic effect that improves the fat digestibility of the edible composition. Appellants refer to FIG. 1 of the specification, to show that a composition that increases fat digestibility also increases the absorption capacity of Vitamin E by the body of the animal, (specification, page 13, and lines20-25). Appellants explain the experimental design and results on page 15 to 18. Appellants further argue that it is not required to

submit individual results for each individual cat and the instant specification provides sufficient data and evidence. Appellants then contend that patentability does not depend on demonstration of explicit data results, an example may be working or prophetic.....on page 18 appellants submit that sufficient data and evidences submitted for the claimed invention. Appellants further add that to provide data for every kind of fat and lipid will be burdensome.

Appellant's arguments are not persuasive with respect to insufficient details in declaration as pointed out earlier in advisory action and have been repeated herein once again: First appellants show in figure 2, percent of cats that showed improvement, however no statistical data of percent of lipid absorption is shown in various cats. There is no fat digestion data presented so that comparison of cats with low or high absorption of fat with respect to consuming diet with only **citric acid, or taurine or fish oil** can be compared with cats that consumed diet with combination of the three ingredients such as citric acid, taurine and fish oil. The graph only shows percent of fat digestibility and percent of cats showing improvement, however, no comparative data for individual cat is shown in terms of lipid absorption. Appellants arguments that instant specification and examples show sufficient data and patentability does not depend upon demonstration of working or prophetic examples is not persuasive because in order to overcome the obviousness rejections by providing unexpected results, evidence in the form of experimental, technical/statistical results should be significant and substantial and the results shall be commensurate with the scope of the claimed invention.

In the instant case the declaration lacks sufficient evidence of lipid absorption. One aspect of the declaration is that the unexpected results shall commensurate with scope of claims, in the instant case, the unexpected results presented by applicants do not show if unexpected fat digestibility and vitamin E absorption will also exist with lower limits of taurine and fish oil. Instant claims also do not recite any specific acidifier with specific amount or range for pancreatic function promoter and no specific acid such as citric acid is recited in instant claims, the claims recite acidifier generically. No data is presented to show unexpected results due to other pancreatic function promoters such as any acidifier. The unexpected results do not commensurate with the entire scope of the instant claims since no results have been shown with respect to any/every acidifier (claimed as pancreatic function promoter) that possibly exist in veterinary art. As such, the declaration is insufficient to overcome the rejections and does not commensurate with the entire scope of instant claims. Appellant's argument that providing data for every lipid and fat would be burdensome is moot in light of withdrawal of 35 USC 112.2 rejections.

Rejection 2:

Appellant argues that a *prima facie case* of obviousness has not been established by the office and the rejections shall therefore be withdrawn. Appellants argue that In contrast to the present claims, *Fuchs, Pearson,Simpson, Watson, DeMichele and Margolin* alone or in combination fail to disclose or suggest a liver

function-promoter comprising taurine ranging between about 0.1% and about 1% by weight of the edible composition on a dry matter basis as required independent Claims 35, 52 and 61 and *Fuchs, Pearson, Simpson, Watson, DeMichele* and *Margolin* fail to disclose or suggest the specific combination of the acidifier, taurine and fish oil in a single edible composition for improving or maintaining absorption of vitamin E in a cat as recited by independent Claims 35, 52 and 61. *Appellants further add that Fuchs* teaches use of emulsifiers and taurine, but without any usage levels. *Pearson* is said to disclose that taurine can be used to enhance absorption of a drug. *Watson* and *DeMichele* fail to teach the use of or even mention any taurine. The Examiner relies on *DeMichele* for a disclosure of fish oil and *Simpson and Margolin* to arguably teach lipid assimilation, these references however, fail to disclose or suggest the claimed range of the liver function-promoter and specific combination of components in accordance with Claims 35, 52 and 61.

Appellant's arguments are not persuasive. In response to appellants argument that the references fail to disclose or suggest the claimed invention alone or in combination, it is respectfully pointed out that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's arguments

against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.1986). In response to appellant's arguments that the reference does not teach the claimed range of taurine, the Examiner respectfully points out that Fuchs et al. teach the amount of Whey protein to be 4.8% and vitamins and minerals to be at least 5% of RDA in example 1 on page 13. It is to be noted that vitamins is taught in instant specification as liver function promoter. Fuchs et al. also teach vitamins in 5% amount, therefore, one of ordinary skill would have envisaged utilizing another liver function promoter (taurine disclosed by the prior art) with an expectation to obtain similar results because Pearson et al. teach that bile salts are synthesized in the liver from cholesterol conjugated with **taurine** and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25. (Thus bile salt with taurine plays important role in fat absorption. Furthermore, since Simpson teaches that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids and a defect in either the absorption or digestion of lipid can lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids, therefore, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health, a skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by Fuchs et al. in order to help in lipid absorption motivated by the teachings of Pearson

et al. and would expect improvement in vitamin E absorption in light of the teachings of Simpson et al. which teaches that vitamin E deficiency occurs due to defect in lipid absorption.

Appellants argue that the declaration provides unexpected results. Appellants argue that the claimed edible composition comprising an acidifier, taurine ranging between about 0.1% and about 1% by weight of the edible composition, and fish oil ranging between about 0.1% and 20% by weight of the edible composition creates a synergistic effect that improves the fat digestibility of the edible composition. Appellants refer to FIG. 1 of the specification, to show that a composition that increases fat digestibility also increases the absorption capacity of Vitamin E by the body of the animal, (specification, page 13, and lines20-25). Appellants explain the experimental design and results on pages 20-24. Appellants further argue that in light of unexpected results the rejections shall be withdrawn because none of the references alone or in combination teach the synergistic unexpected results.

Appellant's arguments are not persuasive with respect to insufficient details in declaration as pointed out earlier in advisory action and have been repeated herein once again: First appellants show in figure 2, percent of cats that showed improvement, however no statistical data of percent of lipid absorption is shown in various cats. There is no fat digestion data presented so that comparison of cats with low or high absorption of fat with respect to consuming diet with only **citric acid, or taurine or fish oil** can be

compared with cats that consumed diet with combination of the three ingredients such as citric acid, taurine and fish oil. The graph only shows percent of fat digestibility and percent of cats showing improvement, however, no comparative data for individual cat is shown in terms of lipid absorption. Appellants arguments that instant specification and examples show sufficient data and patentability does not depend upon demonstration of working or prophetic examples is not persuasive because in order to overcome the obviousness rejections by providing unexpected results, evidence in the form of experimental, technical/statistical results should be significant and substantial and the results shall be commensurate with the scope of the claimed invention.

In the instant case, the declaration lacks sufficient evidence of lipid absorption. One aspect of the declaration is that the unexpected results shall commensurate with scope of claims, in the instant case, the unexpected results presented by applicants do not show if unexpected fat digestibility and vitamin E absorption will also exist with lower limits of taurine and fish oil. Instant claims also do not recite any specific acidifier with specific amount or range for pancreatic function promoter and no specific acid such as citric acid is recited in instant claims, the claims recite acidifier generically. No data is presented to show unexpected results due to other pancreatic function promoters such as any acidifier. The unexpected results do not commensurate with the entire scope of the instant claims since no results have been shown with respect to any/every acidifier (claimed as pancreatic function promoter) that possibly exist in veterinary art. As such, the declaration is insufficient to overcome the rejections and does not commensurate with the entire scope of instant claims.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Snigdha Maewall/

Examiner, Art Unit 1612

Conferees:

Kishore Gollamudi, PhD

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612